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| 09/845,046 | 04/26/2001 | David M. Cobb | PET-01C | 1454 |
| 34313 7590 05/07/2007 ORRICK, HERRINGTON & SUTCLIFFE, LLP IP PROSECUTION DEPARTMENT 4 PARK PLAZA SUITE 1600 IRVINE, CA 92614-2558 | | | EXAMINER NAJARIAN, LENA | |
| | | | ART UNIT 3626 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/845,046

Applicant(s)

COBB ET AL.

Examiner

Lena Najarian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-35 is/are pending in the application.
- 4a) Of the above claim(s) 21-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Request for Continued Examination (RCE) filed 2/7/07. Claims 11, 12, 14, 15, and 18 have been amended. Claims 1-10 have been cancelled. Claims 21-35 are withdrawn. Claims 11-35 are pending.

Drawings

2. The objection to the drawings is hereby withdrawn due to the amendment filed 2/7/07.

Claim Objections

3. The objection to claim 15 is hereby withdrawn due to the amendment filed 2/7/07.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Momich et al. (US 6,335,907 B1) in view of Engel et al. (US 2002/0069085 A1), and further in view of Walker et al. (5,673,944).

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(A) Referring to claim 11, Momich discloses a system for acquiring and tracking data related to medical products being administered to patients, comprising (col. 4, lines 18-29 and col. 17, lines 34-41 of Momich):

containers comprising a medical product therein (Fig. 15 and col. 5, lines 9-11 of Momich);

a read/write communications device attached to each container, the read/write device storing product data including product identification data (col. 1, lines 6-12 and abstract of Momich); and

a plurality of providers each having a reader for obtaining the product data from read/write communications device, and for storing personal records on respective cards, and (col. 6, lines 20-29, col. 10, lines 45-56, Fig. 22, col. 11, lines 30-58, and col. 15, lines 13-20 of Momich)

a provider computer for receiving the product data (Fig. 22 and col. 10, lines 45-56 of Momich).

Momich does not disclose that the medical product is an immunization, the data includes demographic data and records of immunizations and transferring the data and records to an immunization tracking authority while limiting access to the identity of the patient to thereby develop a database of immunization data.

Engel discloses demographic data and limiting access to the identity of the patient (para. 50, para. 37, and para. 60 of Engel).

Walker discloses that the medical product is an immunization (col. 2, lines 57-63 of Walker), immunization records (col. 6, lines 15-21 of Walker), and transferring data

and records to an immunization tracking authority and developing a database of immunization data (col. 6, lines 15-21 and col. 2, lines 57-66 of Walker).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Engel and Walker within Momich. The motivation for doing so would have been to include basic and pertinent information about a patient, to maintain privacy and security, (para. 50, para. 45, and para. 37 of Engel) and to keep immunization records accurate and up to date (col. 1, lines 14-17 of Walker).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 12, Momich discloses wherein the read-write communications device comprises a microchip having non-volatile memory storing the product data (col. 17, lines 48-50 of Momich).

(C) Referring to claim 13, Momich discloses a writer for transferring the product data to the read/write communications device (Fig. 22 and col. 7, lines 47-62 of Momich).

(D) Referring to claim 14, Momich discloses wherein each container comprises a unit dose container comprising a dosage of the medical product for administration to only one individual (col. 8, lines 35-39 and col. 4, lines 18-29 of Momich).

(E) Referring to claim 15, Momich discloses a method for acquiring and tracking data related to medical products being administered to patients, the method comprising (col. 4, lines 18-29 and col. 17, lines 34-41 of Momich):

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attaching a communications device to product packaging for the medical products, the communications device comprising a non-volatile memory (Fig. 15, col. 5, lines 9-11, and col. 17, lines 48-50 of Momich);

downloading product data to the communications devices, the product data comprising product identification data (col. 7, lines 47-62, abstract, and Fig. 22 of Momich);

shipping the medical products for delivery to providers (col. 8, lines 44-46 and col. 14, lines 39-45 of Momich); and

receiving individual data related to individual patients receiving the medical products, the individual data originating from the provider (col. 4, lines 18-29 and col. 7, line 64 – col. 8, line 8 of Momich).

Momich does not disclose supplying patient data including demographic data to an immunization-tracking authority while limiting access to the identity of the patient to thereby develop a database of immunization data.

Engel discloses demographic data and limiting access to the identity of the patient (para. 50, para. 37, and para. 60 of Engel).

Walker discloses supplying data to an immunization tracking authority and developing a database of immunization data (col. 6, lines 15-21 and col. 2, lines 57-66 of Walker).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Engel and Walker within Momich. The motivation for doing so would have been to include basic and pertinent

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information about a patient, to maintain privacy and security, (para. 50, para. 45, and para. 37 of Engel) and to keep immunization records accurate and up to date (col. 1, lines 14-17 of Walker).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(F) Referring to claim 16, Momich does not expressly disclose wherein the individual data comprises demographic data associated with respective individual patients.

Engel discloses demographic data associated with respective individual patients (see para. 50 of Engel).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Engel within Momich. The motivation for doing so would have been to include basic and pertinent information about a patient (para. 50 and para. 45 of Engel).

(G) Referring to claim 17, Momich does not disclose wherein the individual data excludes personal information capable of identifying respective individual patients.

Engel discloses wherein the individual data excludes personal information capable of identifying respective individual patients (see para. 37 of Engel).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Engel within Momich. The motivation for doing so would have been to remove personal identifying information to maintain privacy and security (para. 37 of Engel).

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(H) Referring to claim 18, Momich discloses wherein the product packaging comprises a container having the medical product therein (col. 5, lines 9-11 of Momich).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(I) Referring to claim 19, Momich discloses uploading the product data at a provider's location; and administering the medical product to an individual (Fig. 22 and abstract of Momich).

(J) Referring to claim 20, Momich discloses entering individual data related to the individual into a tracking file, and including at least a portion of the product data in the tracking file (col. 15, lines 21-34 of Momich).

Response to Arguments

6. Applicant's arguments filed 2/7/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 2/7/07.

(1) Applicant argues that the combination of three references by the Examiner is inappropriate inasmuch as there would be no incentive nor suggestion to combine the diverse teachings of these three patents.

(A) As per the first argument, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce

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the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner respectfully submits that the motivations to combine came directly from the references.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ln
In
4-20-07

Robert Morgan
Robert Morgan
Patent Examiner
Art Unit 3626